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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,722	10/22/2003	Peter Dwight Spohn	49276-DIV2 (70545)	6840
21874	7590	09/12/2005		EXAMINER
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EASHOO, MARK	
			ART UNIT	PAPER NUMBER
			1732	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/691,722	SPOHN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark Eashoo, Ph.D.	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 April 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D.11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 20-29 is/are rejected.
- 7) Claim(s) 26 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

*This Office action is in response to the telephone interview on 14-APR-2005 between Ex. C. S. Williams and applicant's attorney, Ms. C. O'Day.*

***Information Disclosure Statement***

The information disclosure statement filed 01-JUN-2004 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information referred to therein has been considered as to the merits.

***Claim Objections***

Claim 26 is objected to because of the following informalities: the claim ends with a typo, namely two periods. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Llewellyn et al. (US 2,685,707) when taken with Slade (US Pat. 3,008,187).

Llewellyn et al. teaches the claimed extrusion process, comprising: providing a PTFE perform (12:60-75); extruding the perform into tubing (1:35-45 and 13:40-55); drying the extrudate or removing the lubricant by volatilization (3:15-45); and curing/sintering the extrudate (13:15-45). Slade provides evidence that the process of Llewellyn et al. forms tubing that is easily split (2:10-35).

The examiner recognizes that all of the claimed effects and physical properties (eg. peel strength) are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Llewellyn et al. (US 2,685,707) in view of Applicant's admission (US 2004/0082913), and Klein et al. (US Pat. 5,334,157), when taken with Slade (US Pat. 3,008,187).

Llewellyn et al. teaches the claimed extrusion process, comprising: providing a PTFE perform (12:60-75); extruding the perform into tubing (1:35-45 and 13:40-55); drying the extrudate or removing the lubricant by volatilization (3:15-45); curing/sintering the extrudate (13:15-45); and fillers (10:50-65). Slade provides evidence that the process of Llewellyn et al. forms tubing that is easily split (2:10-35).

The examiner recognizes that all of the claimed effects and physical properties (eg. peel strength) are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

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Llewellyn et al. does not teach adding a filler for X-ray visualization. Nonetheless, Applicant admits that fillers for X-ray visualization in PTFE catheters/cannula are known in the medical tubing art (para. 10). At the time of invention a person of ordinary skill in the art would have found it obvious to have added a filler for X-ray visualization, as commonly practiced in the art, in the process of Llewellyn et al., and would have been motivated to do so in order to aid guiding of the PTFE tubing when the tubing is used as a catheter/cannula.

Llewellyn et al. does not teach a thermally tipping process. Nonetheless, Applicant admits that thermal tipping processes are conventional in the medical tubing art (para. 29). At the time of invention a person of ordinary skill in the art would have found it obvious to have used a thermal tipping process, as commonly practiced in the art, in the process of Llewellyn et al., and would have been motivated to do so in order to aid insertion of the PTFE tubing into a patient when the tubing is used as a catheter/cannula.

Llewellyn et al. does not teach affixing a hub or a plurality of wing portions to a tube. Nonetheless, Klein et al. teaches affixing a hub or a plurality of wing portions to a tube by molding or the use of an adhesive (4:20-50). At the time of invention a person of ordinary skill in the art would have found it obvious to have affixed a hub or a plurality of wing portions to a tube, as taught by Klein et al., in the process of Llewellyn et al., and would have been motivated to do so because Klein suggests that such attachment of the hub and wings allow the tubing is used as a catheter introducer (ie. another use or economic benefit for the tubing).

Claim 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Llewellyn et al. (US 2,685,707) in view of Calcote et al. (US Pat. 5,453,235), Applicant's admission (US 2004/0082913), and Klein et al. (US Pat. 5,334,157), when taken with Slade (US Pat. 3,008,187).

Llewellyn et al. teaches the claimed extrusion process, comprising: providing a PTFE perform (12:60-75); extruding the perform into tubing (1:35-45 and 13:40-55); drying the extrudate or removing the lubricant by volatilization (3:15-45); curing/sintering the extrudate (13:15-45); and fillers (10:50-65). Slade provides evidence that the process of Llewellyn et al. forms tubing that is easily split (2:10-35).

The examiner recognizes that all of the claimed effects and physical properties (eg. peel strength) are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Llewellyn et al. does not teach coextruding first and second preforms into tubing. Nonetheless, Calcote et al. teaches coextruding first and second preforms into tubing (abstract and 3:25-55). At the time of invention a person of ordinary skill in the art would have found it obvious to have coextruded first and second preforms into tubing, as taught by Calcote et al., in the process of Llewellyn et al., and would have been motivated to do so because Calcote suggests that coextrusion allows for inner and outer surfaces to be tailored to specific needs during use (eg. porosity, lubricity).

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Llewellyn et al. does not teach adding a filler for X-ray visualization. Nonetheless, Applicant admits that fillers for X-ray visualization in PTFE catheters/cannula are known in the medical tubing art (para. 10). At the time of invention a person of ordinary skill in the art would have found it obvious to have added a filler for X-ray visualization, as commonly practiced in the art, in the process of Llewellyn et al., and would have been motivated to do so in order to aid guiding of the PTFE tubing when the tubing is used as a catheter/cannula.

Llewellyn et al. does not teach a thermally tipping process. Nonetheless, Applicant admits that thermal tipping processes are conventional in the medical tubing art (para. 29). At the time of invention a person of ordinary skill in the art would have found it obvious to have used a thermal tipping process, as commonly practiced in the art, in the process of Llewellyn et al., and would have been motivated to do so in order to aid insertion of the PTFE tubing into a patient when the tubing is used as a catheter/cannula.

Llewellyn et al. does not teach a affixing a hub or a plurality of wing portions to a tube. Nonetheless, Klein et al. teaches affixing a hub or a plurality of wing portions to a tube by molding or the use of an adhesive (4:20-50). At the time of invention a person of ordinary skill in the art would have found it obvious to have affixed a hub or a plurality of wing portions to a tube, as taught by Klein et al., in the process of Llewellyn et al., and would have been motivated to do so because Klein suggest that such attachment of the hub and wings allow the tubing is used as a catheter introducer (ie. another use or economic benefit for the tubing).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached form PTO-892.

#### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

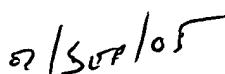
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Eashoo, Ph.D.  
Primary Examiner  
Art Unit 1732

7 September 2005  
me



7/Sept/05